K001564

V. 510(k) SUMMARY

Safety and effectiveness information concerning this device is summarized below. Because this is not a CLASS III device, the special certification defined in this section is not required.

Submitted by: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

Contact Person: David B. Jones

Date Prepared: May 18, 2000

Device Name: SCAN® LT40 (40 channels)

Common Name: Electroencephalograph (EEG)

Classification Name: Electroencephalograph (GWQ)

Device Classification Class II: 21 CFR §: 882.1400 Electroencephalograph

Predicate Device	510(k)	Name
Cadwell Laboratories	K971214	Kilowin (Easy II)

Device Description and Summary of Technological Characteristics:

The Neurosoft SCAN® LT40 is a 40-channel EEG amplifier capable of direct current (DC) recordings, including signal amplification, analog-to-digital conversion, and filtering. SCAN® LT40 permits high-speed simultaneous sampling, acquisition and transfer of data host computer that controls, displays, and stores the acquired data. SCAN®'s software routines separately control each channel and perform real-time digital filtering. SCAN®'s software measures and analyzes EEG signals and performs analysis of complete data sets, calculates compressed spectrum arrays (CSA), and presents results as annotated signal plots or topographic/ tomographic maps in real-time two or three-dimensional (2/3-D) context. SCAN® LT40 is optically isolated and transformers are available for line voltages of 100, 120, 230 VAC.

The Neurosoft SCAN® LT40 systems works in the same manner as each of the approved and predicate devices, and:

- permits 1 to 40 channel configurations, and
- simplifies the acquisition, recording and analysis of the data generated.

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Indications For Use:

The Neurosoft SCAN® LT40 system is intended for the measuring, recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG.

Patient Population:

Adults, children and infants.

Summary of Non-Clinical Testing:

The following is a list of tests performed on the Neurosoft SCAN® LT40 system. These tests demonstrate that the performance of the system is equivalent to that of the predicate devices in the terms of safety and effectiveness, and that the additional features provide utility and product performance which exceeds that of the predicate devices. All tests were completed satisfactorily without adverse report.

The Neurosoft SCAN® LT40 system was designed, and is manufactured and tested to comply with:

- IEC-60601-1,
- IEC-60601-1-1,
- IEC-60601-1-1-2,
- IEC-60601-1-1-4,
- IEC-60601-1-2-26,
- EN ISO 9001,
- EN 46001,
- MDD 93/42/EEC,
- AAMI EC53-1995, and
- CDRH Guidance Document on the "Performance Standard for Electrode Lead Wires and Patient Cables," March 9, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2000

Mr. David B. Jones
Regulatory Affairs, Quality Assurance Manager
Neuro Scan Labs
5700 Cromo Drive, Suite 100
El Paso, Texas 79912-5538

Re: K001564
Trade Name: Neurosoft SCAN® LT40 System
Regulatory Class: II
Product Code: GWQ
Dated: August 21, 2000
Received: September 20, 2000

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Statement of Indications for Use

Applicant: Neurosoft, Inc.
45150 Business Court, Suite 100
Sterling, VA 20166
Phone: (703) 904-9600
Fax: (703) 904-7870

510(k) Number: K001564

Device Name: Neurosoft **SCAN® LT40** system

Indications For Use: The Neurosoft **SCAN® LT40** system is intended for the measuring, recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative
510(k) Number K001564

Prescription Use ✓ or Over-the-Counter _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)